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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,113	03/15/2002	Juerg Lareida	000364.00124	8075

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,113	LAREIDA, JUERG	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5,7,8,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5,7,8,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed January 13, 2006 have been received and entered into the application.

Action Summary

The rejection of claims 2, 3, 5, 7 and 8 under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn in view of Applicant's amendment.

The rejection of claims 2, 3, 5, 7 and 8 under 35 U.S.C. 103(a) as being unpatentable over Du Bois (U.S.Patent No. 6,399,601B1) in view of Ratsimamanga et al. (U.S.Patent No. 5,972,342) and further in view of Clary et al. (U.S.Patent No. 5,753,225), all of record is being maintained for the reasons stated in the previous Office Action and the rejection is modified in this Office Action to include newly added claims 15 and 16.

Response to Arguments

Applicant's arguments filed January 13, 2006 have been fully considered but they are not persuasive. Applicants essentially argue that '601 patent (Du Bois) requires that compound of Formula I be present in the composition to treat diabetes

complications and it fails to teach or suggest that sildenafil can be used alone, without a compound of Formula I of the '601 patent. This is not persuasive because Applicant's broad claim 5, drawn to a method for a chemotherapeutic treatment a neuropathy characterized by application to a patient in need thereof from 1-100mg/day of a pharmaceutical agent **comprising** a compound of formula (I):.." does not exclude the compounds taught by Du Bois, (particularly, the compound of Formula I of Du Bois). Therefore, it would have been obvious to one of ordinary skill in the art to employ the composition comprising sildenafil for the treatment of diabetic complications including various types of neuropathies taught by Du Bois. Applicant's further argue that the present method utilizes sildenafil to treat neuropathies, not to treat diabetes as in Examples 1 and 2 of the sildenafil to achieve an improvement of symptomatic pain and the symptoms and complications from diabetes, but not the disease itself. This is not persuasive because the data has been carefully considered and reviewed. However, the method is indistinguishable over Du Bois reference because Du Bois teaches the treatment of diabetes includes the diabetic complications including the various forms of neuropathies and Du Bois report that sildenafil is useful for treatment of diabetes which would also include the treatment of diabetic complications as taught by Du Bois. It is noted that Example 1 of the instant specification teaches the employment of sildenafil in diabetic patients suffering from suffering from diabetic complications having erectile dysfunction and the Example 2 also shows the same subject population suffering from diabetes having complications of diabetes. For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented

by the cited references because it would have been obvious to one of ordain skill in the art to employ sildenafil comprising composition taught by Du Bois for the treatment of diabetic patients having diabetic complications of various neuropathies therein. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

Claims 2, 3, 5, 7, 8, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Du Bois (U.S.Patent No. 6,399,601B1) in view of Ratsimamanga et al. (U.S.Patent No. 5,972,342) and further in view of Clary et al. (U.S.Patent No. 5,753,225), all of record.

Du Bois teaches a pharmaceutical composition comprising sildenafil for the treatment of diabetic complications such as diabetic neuropathy (metabolic neuropathy), and retinopathy. (abstract, column 23, line 63 through column 24, line 39, particularly, column 24, line 38). Du Bois teaches treatment of diabetic complication, such as neuropathy, nephropathy, retinopathy are included in the treatment of diabetes. (column 23, line 67 though column 24, line 2). Dubois teaches that sildenafil is a representative agent that can be used to treat diabetes. (column 24, lines 18-39).

Du Bois does not teach the specified amounts set forth in claim 5 and peripheral diabetic polyneuropathy, gastroparesis and a toxic neuropathy set forth in claims 5, 15 and 16.

Ratsimamanga et al. teach diabetic neuropathy in its various forms including peripheral polyneuropathy, paresthesias and autonomous neuropathies. (column 9, lines 40-45).

Clary et al. teach etiologies of peripheral neuropathies and polyneuropathy include toxic agents and metabolic causes. (column 2, lines 37-47).

It would have been obvious to one of ordinary skill in the art to employ sildenafil comprising composition taught by Du Bois for the treatment of diabetic neuropathy set forth in claim 5, including peripheral polyneuropathy, paresthesias and autonomous neuropathies and also treat the etiology of peripheral neuropathies including polyneuropathy (toxic neuropathies and metabolic neuropathies) because the specified neuropathies set forth in claim 5 are the various forms of diabetic neuropathies and because Du Bois teaches that the composition comprising sildenafil is useful for the treatment of diabetic neuropathies which encompasses various forms including peripheral polyneuropathy, paresthesias and autonomous neuropathies, and peripheral polyneuropathy which is caused by toxic neuropathies and metabolic neuropathies as taught by Ratsimamanga et al. and Clary et al. respectively. To optimize the amount of sildenafil for the treatment of diabetic neuropathies is obvious because Du Bois teaches that sildenafil comprising composition is useful for the treatment of diabetic complications such as diabetic neuropathy encompassing various forms. One would

have been motivated to employ the composition comprising sildenafil taught by Du Bois for the treatment of any basic forms of diabetic neuropathy including peripheral polyneuropathy caused by toxic agents and metabolic conditions, paresthesias and autonomous neuropathies by administration of sildenafil in order to achieve effective treatment of diabetic neuropathy in general as taught by Du Bois et al.

For these reasons the claimed subject matter deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

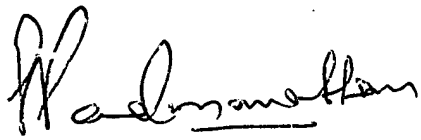
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
April 25, 2006